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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11 19 2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/749,637

**Applicant(s)**

OLIVERA ET AL.

**Examiner**

Gabriele E. BUGAISKY

**Art Unit**

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,6,9,11-14 and 36-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 18-35 is/are rejected.
- 7) ☐ Claim(s) 1-2, 5, 7-8, 10, 15-17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>Z</u> . | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1653

**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of  $\sigma$ Striatus26 and its propeptide in Paper No. 10 is acknowledged. The traversal is on the ground(s) that The traversal is on the ground(s) that a particular class of conotoxins will share a conserved cysteine framework, disulfide bridging pattern and conserved molecular target. and that there is no serious search burden. . This is not found persuasive because while it is agreed that that the  $\alpha$ - conotoxins share a general 3 dimensional structure and share a similar cysteine framework and disulfide bridging pattern, there indeed is a serious search burden. The Examiner is of necessity limited to the search tools at hand. No generic formula for the O-superfamily has been presented. For search purposes, the Examiner does however, consider , a propeptide along with the mature protein, and, e.g., a modified Trp such as those recited in claim 10, to be the same as Trp. Applicant states that a single subclass covers all the of the peptides., and the search is the same for all of the peptides.; Applicant has incorrectly stated the subclass; peptides of 25-100 amino acids are classified in Class 530, subclass 324, presently with over 2500 patents While a general word search and search of the subclass is performed, the Examiner disagrees with the Applicant's position. in that a search for the specific peptides must be made and that a computer search for more than a single specific peptide indeed constitutes a severe burden. The sequence databases are growing at an incredible rate, specific searches for each claimed sequences must be performed and the Examiner is not given unlimited search time and resources The search constitutes AT PRESENT a serious burden. The Examiner can only operate with the search tools currently available to her. The requirement is still deemed proper and is therefore made FINAL.

Art Unit: 1653

Claims 3-4, 6, 9, 11-14 and 36-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Information Disclosure Statement***

The listing of references in the specification (pages 98-100) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or by Applicants on PTO-1449, they have not been considered.

#### ***Specification***

Applicants are required under 37 C.F.R. 1.821-1.825 to amend their claims to specific sequences by citing the appropriate SEQ ID Nos. Please note that Xaa4 and Xaa3 of  $\sigma$ Striatus26

Art Unit: 1653

in Table 1 are not the 3<sup>rd</sup> and 4<sup>th</sup> amino acids, respectively, of SEQ ID NO: 271; rather, they are aa1 and aa4, respectively. The amendments should reflect the amino acid numbers of the SEQ ID No.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The disclosure is objected to because of the following informalities: reference is made to a US application, but the space is blank (page 11), line 9.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. (e.g., page 1, line 29) Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

### ***Claim Objections***

Claims 1-2, 5, 7-8, 10 and 15-35 are objected to because of the following informalities: they read upon non-elected subject matter.

Claims 1 and 2 also recite sequences contained in Tables, not SEQ ID Nos.

Claims 18 and 19, line 3 of each, and claims 30 and 31, line 4 of each, all recite the word "acceptable". This presumably should be "acceptable".

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are all directed to methods of use; claim 18 is directed to a method of regulating sodium flow through sodium channels, claims 19-29 are directed to methods of treating disorders associated with voltage gated ion channel disorders, claim 30 is directed to a method of alleviating pain and claims 31-35 are directed to a treatment method that activates  $K_{ATP}$  channels. Applicants have obtained a novel conotoxin  $\sigma$ Striatin26 which, like all conotoxins, is presumed to act specifically upon a specific membrane bound channel; however, there is no evidence on the record to show the specificity of this conotoxin. As stated by McIntosh (reference 16 of paper # 7) on page 606, final paragraph, "For neurobiologists, the major interest in *Conus* peptides is that they are highly subtype-specific ligands. For several ion channel targets, *Conus* peptides are the most specific ligands known. . . This high subtype selectivity is proving to be a general feature of *Conus* peptides"

Each set of the above claims is directed to treatment of a different channel; thus, it appears that at the time of filing of this application, Applicants had not biochemically characterized the mode of action of  $\sigma$ Striatin26. Without such information, one may not

Art Unit: 1653

extrapolate which treatment methods would likely be feasible for  $\sigma$ Striatum26. It thus appears premature to claim specific treatment methods using  $\sigma$ Striatum26 that are directed to different ion channels.

Claims 18-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As stated above, what has not been described cannot be considered enabled..

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 20, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). In addition, "reversal of the actions of curare and other neuromuscular blocking drugs" is not a disorder.

### ***Conclusion***

No claims are allowed.  $\sigma$ Striatum26 conotoxin and its precursor peptide are deemed free of the prior art.

Art Unit: 1653

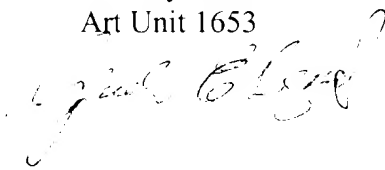
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15 AM-1:30 PM Wed. and Fri, and 8:15-2:PM Tu and Th..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.

November 13, 2002

Gabriele E. BUGAISKY  
Primary Examiner  
Art Unit 1653

  
**GABRIELLE BUGAISKY**  
**PRIMARY EXAMINER**